In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 13, 2021

C.L.S.,	*	PUBLISHED
Petitioner,	*	No. 19-1955V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal Decision; Diphtheria, Pertussis, and Tetanus ("DPT") Vaccines; Equitable Tolling.
Respondent.	*	

C.L.S., pro se, Asheville, NC, for petitioner.
Heather Lynn Pearlman, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

I. INTRODUCTION

On December 27, 2019, C.L.S. ("petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleged that he sustained injuries, including "Autoimmune Disorders, psychic injury and trauma, loss of wages and productivity, excessive medical expenses, decreased quality of life, collateral damage, and challenge to fulfilling all God-given potential," resulting from adverse effects of diphtheria, pertussis, and tetanus ("DPT") vaccinations received

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

on June 29, 1987, September 1, 1987, January 15, 1988, July 13, 1990, and July 9, 1991. Petition at Preamble (ECF No. 1). Petitioner alleged that his "illness, symptoms[,] and chronic condition have lasted since [his] first DPT vaccine administration on June 29, 1987 and have compounded since then." Id. at 6.

Respondent filed a Motion to Dismiss on March 25, 2020, stating "petitioner filed his claim for compensation well after the expiration of the statutorily prescribed limitations periods set forth in Section 16(a) of the Vaccine Act" and "has not demonstrated the extraordinary circumstances necessary to equitably toll the Act's statute of limitation." Respondent's Motion to Dismiss ("Resp. Mot."), filed Mar. 25, 2020, at 1-2 (ECF No. 15). Therefore, respondent argues that the case should be dismissed. Id. at 2.

Based on the reasons set forth below, the undersigned **GRANTS** respondent's motion to dismiss and **DISMISSES** petitioner's case for failure to file a timely action pursuant to Section 16(a) of the Vaccine Act. In summary, the undersigned finds petitioner's statute of limitations expired before petitioner's alleged period of incapacitation began on October 1, 2013. Specifically, the undersigned finds petitioner's symptoms were present for more than 36 months prior to October 1, 2013. The undersigned also finds that the question of whether equitable tolling should be applied is irrelevant.

II. BACKGROUND

A. Procedural History

Petitioner filed his claim on December 27, 2019, along with 36 exhibits consisting of his birth certificate, medical records, Social Security Administration ("SSA") records, medical literature, and resume. Petition; Petitioner's Exhibits ("Pet. Exs.") 1-36.

On January 9, 2020, this case was reassigned to the undersigned. Notice of Reassignment dated Jan. 9, 2020 (ECF No. 7). Petitioner filed a letter, affidavit, and a statement of completion that same day. Pet. Exs. 37-38; Statement of Completion, filed Jan. 9, 2020 (ECF No. 9).

On January 15, 2020, the undersigned issued an order to show cause. Order to Show Cause dated Jan. 14, 2020 (ECF No. 10). The undersigned explained that upon review of petitioner's claim, petitioner filed his claim more than 36 months after he alleged that he first experienced symptoms, which was in 1987. Id. at 1. Petitioner was ordered to file any evidence showing why his petition should not be dismissed. Id. On February 3, 2020, petitioner filed a response to the Order to Show Cause. Pet. Exs. 39-40.

On March 25, 2020, respondent filed a Motion to Dismiss instead of a Rule 4(c) Report, arguing petitioner did not file his claim within the statutorily prescribed limitations period set forth in Section 16(a) and has not demonstrated extraordinary circumstances necessary for equitable tolling. Resp. Mot. at 1-2. On April 28, 2020, petitioner filed a motion to proceed along with a letter from a physical therapist, medical records, his high school transcript, and his

transcript from Northeastern University. Pet. Mot. to Proceed, filed Apr. 28, 2020 (ECF No. 20) (filed as Pet. Ex. 42); Pet. Exs. 43-47.

A status conference was held on May 20, 2020. Order dated May 20, 2020 (ECF No. 23). The undersigned explained that after a review of the records, her preliminary finding was that the statute of limitations had expired on petitioner's claim. Id. at 1. Although petitioner argued equitable tolling applies, the undersigned did not see any evidence suggesting the entire time since receipt of vaccinations was eligible for tolling. Id. Because of COVID-19, the undersigned gave petitioner additional time to file any additional documents or records showing his claim was not time-barred. Id.

On July 20, 2020, petitioner filed a response entitled "Additional Evidence that Claim Isn't Time-Barred," along with medical literature, CVs, and an expert report from Judy A. Mikovits, Ph.D. and Francis W. Ruscetti, Ph.D.[3] Pet. Additional Evidence that Claim Isn't Time-Barred ("Pet. Response"), filed July 20, 2020 (ECF No. 24); Pet. Exs. 48-50. Respondent filed a reply to petitioner's response on September 25, 2020. Resp. Reply to Pet. Response ("Resp. Reply"), filed Sept. 25, 2020 (ECF No. 28).

Thereafter, the undersigned afforded the parties an additional 30 days to file any additional evidence in this matter before closing the evidentiary record. Order dated Sept. 25, 2020 (ECF No. 29). No additional evidence was filed by the parties.

This matter is now ripe for adjudication on respondent's motion to dismiss.

B. Summary of Relevant Facts Related to Onset[4]

Petitioner was born on May 12, 1987. Pet. Ex. 1 at 1. On June 29, 1987, petitioner received his first DPT vaccination.[5] Pet. Ex. 2 at 1. Petitioner received his first polio vaccination on July 27, 1987. Id. On September 1, 1987, petitioner received his second DPT vaccination and on October 6, 1987, petitioner received his second polio vaccination. Id. Petitioner received his third DPT and third polio vaccinations on January 15, 1988. Id.

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[3] Petitioner stated that the law firm of Lundy, Lundy, Soileau & South, L.L.P. assisted him in his response entitled "Additional Evidence that Claim Isn't Time-Barred." ECF No. 24-14. Additionally, the expert report from Judy A. Mikovits, Ph.D. and Francis W. Ruscetti, Ph.D. is addressed to Mr. Lundy at this law firm. Pet. Ex. 49 at 1. Petitioner has represented himself throughout the proceedings. Petitioner has not stated or alleged that Mr. Lundy or any attorney at his firm is his attorney in this case. Additionally, no attorney has filed a notice of appearance or otherwise taken steps to be counsel of record for petitioner. Lastly, neither Mr. Matthew Lundy nor Mr. Hunter Lundy are a member of the Court's Bar.

[4] The undersigned has reviewed all of petitioner's medical records, but only summarizes those pertinent to onset issues.

[5] Only petitioner's DPT, polio, and measles, mumps, and rubella ("MMR") vaccinations are noted in this section. For a full history of immunizations, see Pet. Ex. 2 at 1.

Petitioner had childhood illnesses and complaints during his childhood, including fever, cough, sore throat, asthma, and allergies. See Pet. Ex. 2.

Petitioner received his first measles, mumps, and rubella ("MMR") vaccination on August 23, 1988. Pet. Ex. 2 at 1. On July 13, 1990, petitioner received his fourth DPT and fourth polio vaccinations. Id.

Petitioner underwent a speech-language evaluation in April 1991 due to his parents' concerns regarding his speech intelligibility. Pet. Ex. 2 at 10. Under history, petitioner's developmental and speech-language milestones were reported. Id. Medical history was positive for ear infections and a bacterial infection in petitioner's eye at one year. Id. at 11. Tests revealed receptive language abilities were mildly delayed. Id. The impression was petitioner had "mildly delayed play, social, receptive language and expressive[] language skills." Id. at 14. The speech language pathologist recommended petitioner continue speech-language therapy twice a week for half hour sessions, and petitioner's mother agreed. Id. at 15.

On July 9, 1991, petitioner received his fifth DPT and fifth polio vaccinations. Pet. Ex. 2 at 1. Petitioner received his second MMR vaccination on June 27, 1992. Id.

On May 3, 1993, petitioner presented to the emergency room for difficulty breathing due to hypertrophy of the adenoids and tonsils. Pet. Ex. 2 at 6. Examination revealed enlarged tonsils and nasal congestion, which were treated with antibiotics. Id. A tonsillectomy and adenoidectomy were indicated, which he underwent on June 21, 1993. Id. at 6-8. The records indicate that petitioner fully recovered from this surgery. Id.

In December 1995, petitioner was diagnosed with RAD.[6] Pet. Ex. 2 at 49. Petitioner tested negative for Lyme disease antibodies on June 6, 1996 after a tick bite. Id. at 30, 45. On July 1, 1998, petitioner underwent a pediatric cardiology consultation and was found to have a functional heart murmur with no sign of heart disease. Id. at 52.

Petitioner filed his high school transcript for years 2001 to 2005. Pet. Ex. 46. Generally, his grades were good with a final average of 88.0. Id. He participated in numerous clubs, swimming, and fall and spring crew. Id. In May 2005, petitioner was in a major car accident, which he said years later was a suicide attempt. Pet. Ex. 5 at 62; Pet. Ex. 12 at 23; Pet. Ex. 39 at 2-3.

Petitioner attended Northeastern University from 2005 to 2010. Pet. Ex. 47 at 2-4. On May 7, 2010, he was awarded a B.S. in Business Administration. Id. at 2. His overall GPA was 2.917 and his final semester GPA was 3.467. Id. at 4. Petitioner's transcript shows that he attended the requisite classes and semesters to obtain his degree. There is no suggestion that he was unable to perform his school work, or that he had any mental illness which impaired his ability to function during his college years. See id. at 1-5. During his time at Northeastern, he

[6] The record does not define or explain "RAD," but it may be an abbreviation for reactive airway disease.

did have numerous visits to doctors for varying issues, which are described below. See Pet. Ex. 5.

On October 3, 2006, petitioner presented to Dr. Gianmichel D. Corrado and complained of dizziness, palpitations, nausea, lightheaded, and "feeling 'out of it.'" Pet. Ex. 5 at 96. The assessments were dizziness and anxiety. Id. Petitioner was instructed to follow up in one week. Id. at 97. Petitioner returned the next day, October 4, 2006, complaining of nausea, diarrhea, ill feelings, and lightheadedness. Id. at 84. Petitioner was prescribed Prilosec for gastroenteritis and Vicodin for difficulty sleeping, and was instructed to follow up in one week. Id. Petitioner returned to Dr. Corrado on October 12, 2006. Id. at 92. Petitioner reported his symptoms were improving and he was having fewer panic attacks and no palpitations. Id. On October 24, 2006, Dr. Corrado saw petitioner for a follow up on his anxiety. Id. at 89. Petitioner reported mild symptoms of anxiety and depression. Id. The assessment was anxiety. Id. None of these records note that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

From November 2006 to February 2007, petitioner returned to Dr. Corrado for follow up of his anxiety and associated symptoms. Pet. Ex. 5 at 82-83, 87-88. On January 9, 2007, Dr. Corrado "discussed the possibility of anxiety with [petitioner and] he is not ready to consider therapy at this [point]." Id. at 83. None of these records indicate that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

During a follow up exam regarding blood test results on February 20, 2007, Dr. Corrado wrote "will [follow up] [see] mental health in near future." Pet. Ex. 5 at 79. On February 27, 2007, petitioner underwent a Mental Health Assessment with John Dugan on referral from Dr. Corrado. Id. at 78. Petitioner stated he "worr[ies] a lot about heart problems [or other] physical problems." Id. Petitioner had a panic attack in September 2006, and since then, he has had "a series of anxious worries about his body." Id. Petitioner sometimes experiences "light headedness[] or body pains that lead him to believe that he is having a serious problem. He had a pain in the heart, and then he was measured from a stress test. All tests have proved no medical problems." Id. Neither record gives rise to any inference suggesting that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

On March 19, 2007, petitioner visited Dr. Gairy F. Hall with complaints of nausea and diarrhea. Pet. Ex. 5 at 76. Under medical history, anxiety was noted. Id. Under "Hospitalization/Major Diagnostic Procedure," Dr. Hall documented "x 2 anxiety." Id. Dr. Hall did not document that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

Petitioner returned to Dr. Corrado on March 30, 2007, complaining of a cold. Pet. Ex. 5 at 71. On April 3, 2007, petitioner saw Dr. Corrado for a cough. Id. at 69. Anxiety was documented under past medical history in both visits. Id. at 69, 71. These records do not document that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

On May 8, 2007, petitioner saw Dr. Corrado. Pet. Ex. 5 at 66. Petitioner complained of persistent anxiety, feeling of impending doom, no hallucinations, and some difficulty sleeping. Id. The assessment was anxiety and Dr. Corrado "encouraged and offered to help [petitioner] get help and he refuse[d] for now." Id. On May 15, 2007, petitioner returned to Dr. Corrado "to discuss ongoing a[n]xiety/panic." Id. at 64. Dr. Corrado noted petitioner "[c]ontinue[d] to have intermittent panic attacks" and no hallucinations. Id. Dr. Corrado's assessment was anxiety. Id. He added that "[petitioner] has been reluctant to seek mental health counseling. Had one visit which I advised and didn't follow up. I think [petitioner] has been suffering throughout the year with these symptoms and would benefit from counseling," which petitioner agreed to. Id. Neither record suggested that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

Petitioner underwent a second Mental Health Assessment on May 21, 2007. Pet. Ex. 5 at 62. Petitioner complained of anxiety for the past year, since September 2006, with symptoms of "racing heart, headaches, dizziness, dysphoria, shakiness, [and] tingling sensations throughout body." Id. He reported that he was "unsure if his symptoms [were] solely related to anxiety, feeling that there may be something physically not right with him that may be triggering his anxiety (which he states runs in his family)." Id. Petitioner believed he may have "lingering medical complications" associated with his car accident in May 2005, and wanted to "rule out more medical factors before coming to [the] conclusion" that he had anxiety. Id. On examination, petitioner was noted to be fully alert and oriented; had appropriate appearance and behavior; anxious; had no wish, plan, intent, or impulse for suicide or homicide; had no hallucinations or distortions; had no evidence of psychosis; had fair insight; and had intact judgment, concentration, attention, and memory. Id. The assessment was anxiety. Id. at 63.

On June 27, 2007, petitioner filled out an intake form for an initial visit with Dr. Holly Bienenstock. Pet. Ex. 4 at 70.[7] Petitioner noted he had fatigue, poor sleep, nervousness/anxiety, headaches, sore throat, cough, shortness of breath, previous bronchitis, chest pain, and palpitations. Id. He also stated he was not taking any medications. Id.

[7] Petitioner's Exhibit 4 contains records from 2007 to 2013 that are difficult to read. See Pet. Ex. 4 at 62-69. These records note treatment for anxiety and depression, including treatment with medication. Because the records are difficult to read, it is not clear what medications were prescribed, other than Lexapro. On November 4, 2013, there is a note that suggests petitioner was previously on medications, and while this note is very difficult to read, the medications appear to include Lamictal and Ativan. Id. at 62. Lamictal is a trademark for lamotrigine, which is used as an anticonvulsant and is also used as a mood stabilizer for those with bipolar disorder. Lamictal, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=27519 (last visited Mar. 10, 2021); Lamotrigine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=27542 (last visited Mar. 10, 2021). Ativan is a trademark for lorazepam and is used to treat anxiety. Ativan, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4704 (last visited Mar. 10, 2021); Lorazepam, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=28747 (last visited Mar. 10, 2021).

On June 29, 2007, petitioner presented to Dr. Leonard J. Landesberg for evaluation of dyspnea. Pet. Ex. 4 at 13. Petitioner "complain[ed] of shortness of breath and dyspnea on exertion over the last month." Id. Petitioner reported extreme tachycardia during exercise. Id. On examination, Dr. Landesberg noted petitioner was in no acute distress. Id. at 14. His impression was "[d]yspnea on exertion with tachycardia of unclear etiology." Id. at 15. Dr. Landesberg excluded a primary pulmonary and musculoskeletal etiology and noted a cardiac evaluation was underway. Id.

From May 22, 2007 to September 16, 2009, petitioner saw Dr. Corrado various times for unrelated issues including cough, sore throat, allergies, and rash. Pet. Ex. 5 at 2-60. At his visits on October 11, 2007 and September 16, 2009, petitioner also complained of palpitations. Id. at 2, 41. On June 25, 2008, petitioner returned to Dr. Corrado for a referral to counseling. Id. at 21. Anxiety was noted in the past medical history in most of these visits. None of the records document that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

On August 12, 2010, at a follow up visit, Dr. Bienenstock, started petitioner on Lexapro.[8] Pet. Ex. 4 at 64.

On August 26, 2010, petitioner presented to Dr. Landesberg for an evaluation of shortness of breath. Pet. Ex. 4 at 24. Dr. Landesberg noted petitioner "was seen by [him] in 2007 for similar complaints of shortness of breath and palpitations." Id. He added that petitioner "was essentially well for the last three years." Id. Petitioner "describe[d] his feeling of shortness of breath as the inability to take a deep breath and a discomfort in his chest, particularly when having a fast heart rate." Id. Dr. Landesberg's evaluation was unremarkable. Id. at 26. This record does not document that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

Petitioner saw Dr. Anthony S. Cohen on September 10, 2010. Pet. Ex. 4 at 22. Petitioner reported that "he has not been feeling well for the past year or so." Id. His symptoms included shortness of breath, vertigo, imbalance, "floaters in his vision," "stars and other visual phenomenon," slurred speech but no dysphasia, numbness and tingling in different parts of body, muscle spasms, headaches, and tightness in jaw. Id. Petitioner reported "[h]e has never been treated specifically for anxiety but [for] during his college career" and "[n]o medications were prescribed." Id. Neurologic exam was normal, and petitioner was noted to be alert and fully oriented. Id. at 23. Dr. Cohen found petitioner likely had anxiety but found "demyelinating disease" was a possibility. Id.

[8] Lexapro, a trademark for escitalopram oxalate, is an antidepressant. Lexapro, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=28190 (last visited Mar. 10, 2021); Escitalopram Oxalate, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=17302 (last visited Mar. 10, 2021).

On September 30, 2010, petitioner visited Dr. Sharon Chirban at Children's Hospital Boston. Pet. Ex. 4 at 8. Dr. Chirban documented that Dr. Kim Pearson[9] "prescribed a couple of medications to help [petitioner] with acute anxiety and panic disorder."[10] Id. Petitioner was "still on the fence with trying to explore the hypothesis that all of his physical symptoms are truly anxiety." Id. Dr. Chirban added that "[a]s might be expected, he is worried that [medication] will be masking symptoms." Id.

On October 7, 2010, petitioner returned to Dr. Chirban. Pet. Ex. 4 at 10. Petitioner "considered taking the Ativan" but only took it for two days. Id. She encouraged petitioner to continue taking the Ativan and Lexapro to treat his anxiety. Id. Dr. Chirban was "still very, very concerned about physical symptoms of shortness of breath, tingling in his brain" and "[c]ontinu[ed] to reassure him . . . [to] at least eliminate the anxiety from the picture" before determining if petitioner has any other underlying conditions. Id. Petitioner agreed to begin Lexapro. Id.

Petitioner followed up with Dr. Chirban on October 14, 2010 and reported improved symptoms. Pet. Ex. 4 at 11. Petitioner began taking Lexapro, and had been on it for one week. Id. Dr. Chirban documented that petitioner "was feeling distinctly more comfortable than he was a week ago [but] still worr[ied] about loss of physical symptoms but better able to sort of see how his anxious mind interprets physical information and then turns it into something that he then worries about." Id. On October 21, 2010, petitioner returned to Dr. Chirban who noted petitioner was not taking some of his prescribed medications. Id. at 9. Petitioner "missed a dose of his Ativan yesterday and this morning, continuing to experience symptoms of anxiety through shortness of breath." Id. Dr. Chirban added that petitioner "goes to the trouble of getting evaluated and then he does not follow through on the prescription, so he second-guesses, over-thinks." Id. She recommended petitioner take his prescribed medications, fill his Xanax prescription, and see Dr. Pearson. Id. None of Dr. Chirban's records document that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

On December 13, 2010, petitioner presented to Nurse Practitioner, James Hayes, at Fenway Health for a rash. Pet. Ex. 6 at 1. Mr. Hayes noted petitioner had a history of depression and anxiety that was well controlled on Lexapro. Id. Petitioner was noted to see Dr. Pierson[11] in Psychiatry at Arlington Heights for his anxiety and depression. Id. Mr. Hayes' record from this visit does not document that petitioner was incapable of rational thought or

[9] Petitioner did not file any records from Dr. Pearson.

[10] It is not clear from this record what medication Dr. Pearson prescribed to petitioner; however, during petitioner's next visit to Dr. Chirban, she wrote petitioner "considered taking the Ativan." Pet. Ex. 4 at 10. Thus, it is reasonable to believe that Dr. Pearson prescribed Ativan to petitioner sometime before September 30, 2010.

[11] Petitioner did not file any records from Dr. Pierson. It is not clear from the record whether Dr. Pierson and Dr. Pearson are the same person.

deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

On January 3, 2011, petitioner returned to Mr. Hayes, who noted petitioner reported "his Lexapro dose was recently increased to 40mg daily for general anxiety disorder. Followed by a [psychiatrist] and a counselor. No longer on PRN Ativan. Denies interval panic or anxiety attacks. Depression stable as well." Pet. Ex. 6 at 6. On exam, Mr. Hayes noted petitioner was "[s]omewhat anxious, but pleasant. Speech mildly pressured, but coherent. Though[t] processes/content appropriate." Id. at 7. Assessment was "worried well" and "anxiety depression." Id. (emphasis omitted).

Petitioner returned to Fenway Health on March 5, 2011 and saw Physician Assistant, Julie Thompson for an unrelated issue. Pet. Ex. 6 at 8. Under current problems, anxiety and depression were listed. Id. On exam, Ms. Thompson noted "[petitioner] appears well nourished, hydrated, and in no apparent distress." Id. at 9. Petitioner was still prescribed 40mg of Lexapro daily. Id.

On May 2, 2011, petitioner saw Mr. Hayes for a rash. Pet. Ex. 6 at 10. Petitioner "[r]eport[ed] that he decided to taper of[f] the Lexapro, and instead would like to treat his anxiety and depression with diet. . . . Fe[lt] his depression and anxiety remain well controlled, denying exacerbation, [suicidal ideation/homicidal ideation]. . . . Dr. Pierson already aware of patient's approach to his psychiatric symptoms." Id. His record from this visit does not document that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

Petitioner visited Mr. Hayes for a routine follow-up on his anxiety on September 20, 2011. Pet. Ex. 6 at 14. Mr. Hayes documented that petitioner "[h]a[d] decided to send in labwork to a private lab company for a complete nutritional evaluation and telomere study. Concerned that taking Accutane in the past for acne might be playing a role in his anxiety, or that he may have a micronut[r]ient deficiency." Id. On exam, petitioner was "[p]leasant. Speech clear, coherent without being forced. Thought process/content appropriate. [Judgment] and insight intact. Gait smooth and steady." Id. Mr. Hayes encouraged petitioner to consider counseling. Id. at 15.

On October 27, 2011, at a visit to Mr. Hayes, petitioner reported that he "believes that prior use of Accutane has resulted in telomere damage and resultant micronutrient deficiency, depression, fatigue. He would like to undergo specialized telomere analysis in Spain, and has made plans to travel for this in November. . . . Denies other acute concerns today." Pet. Ex. 6 at 18. Mr. Hayes assessed petitioner's anxiety and depression as "improved." Id. at 19. The updated medication list included Lexapro 10mg daily. Id. Petitioner saw Mr. Hayes on November 11, 2011 for a routine follow-up and medication refill for his anxiety and depression. Id. at 20. Petitioner reported "[f]eeling well" and "den[ied] any acute complaints or concerns." Id. Mr. Hayes documented that petitioner's "[a]nxiety and depression well controlled on Lexapro 40mg daily." Id. Petitioner was seeing an outside psychiatrist, but is "transferring psychotropic medication management" to Fenway Health. Id. Mr. Hayes provided a refill for Lexapro. Id. at 21. Mr. Hayes' records from these visits do not document that petitioner was

incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

On December 8, 2011, petitioner underwent a biopsy to test for Celiac disease. Pet. Ex. 7 at 6. "In the appropriate clinical context, the findings [were] consistent with celiac disease" but because of the presence of *Helicobacter pylori* ("*H. pylori*"), "correlation with clinical and serological parameters [was] recommended to determine whether the findings in the duodenum represent celiac disease." Id. On January 13, 2012, petitioner was noted to have been diagnosed with gastritis with *H. pylori* and had a normal celiac panel on December 8, 2011. Pet. Ex. 6 at 22. On January 30, 2012, petitioner was positive for human leukocyte antigen (HLA) DQ2, but "[t]hese antigens are not diagnostic of celiac disease." Pet. Ex. 7 at 5.

Petitioner followed up with Mr. Hayes on February 23, 2012. Pet. Ex. 6 at 24. Mr. Hayes wrote petitioner "would like to taper off the Lexapro, but realizes that he shou[ld] do this very slowly. He is currently on Lexapro 40mg daily. Feels very well otherwise, denying other acute complaints or concerns." Id. On exam, Mr. Hayes documented that petitioner was "[p]leasant. Speech clear, coherent without being forced. Thought process/content appropriate. [Judgment] and insight intact. Gait smooth and steady." Id. at 25. Mr. Hayes provided petitioner with a schedule for tapering off Lexapro. Id.

From September to November 2012, petitioner saw Dr. Andrew Brandeis, N.D.,[12] for varying issues including B12 deficiency, fatigue, and anxiety. Pet. Ex. 8 at 28-34. Petitioner was noted to be in no acute distress during a visit on October 8, 2012. Id. at 31. On October 15, petitioner's chief complaint was "[f]eeling anxious and tired." Id. He was again noted to be in no acute distress. Id. On October 31, petitioner complained of "fatigue, negative thoughts, body feels heavy, [and] feels depressed," and was not experiencing any acute distress. Id. at 33.

On November 28, 2012, petitioner was tested for Lyme disease. Pet. Ex. 8 at 12-17. His results on January 8, 2013 revealed he was negative for the condition. Pet. Ex. 4 at 34; Pet. Ex. 9 at 4.

On February 4, 2013, petitioner saw Dr. Todd LePine at The UltraWellness Center for lab work. Pet. Ex. 11 at 2. Under past medical history, Dr. LePine documented Celiac Disease, palpitations, "[a]utoimmune [d]isease possible," "[d]epression 2010 probably longer," headaches, "[a]nxiety 2006," "[b]rain fog many years tough to think pain," and more. Id. at 3-4. Dr. LePine noted "neg[ative] autoimmune markers." Id. at 3. The primary assessment was depression. Id. at 4. Dr. LePine's records do not document that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

On October 4, 2013, petitioner was admitted to Zucker Hillside Hospital and underwent an initial assessment conducted by Dr. Michael Hoffnung. Pet. Ex. 12 at 1. Petitioner was admitted for disorganized behavior. Id. Dr. Hoffnung wrote petitioner "[r]eport[ed] normal sleep pat[t]ern, elevated, euphoric mood; believing he has special powers of telepathy. He

[12] Presumably, this means Doctor of Naturopathic Medicine.

endorse[d] referential delusions believing a speech he watched on the internet was referring to him and that he could communicate with the speaker; he attribute[d] his new powers to some higher purpose." Id. Petitioner also "report[ed] his mood is slightly down since he hasn't taken Lexapro since yesterday, but otherwise denies any depressive symptoms." Id.

Dr. Hoffnung, after speaking with petitioner's father,[13] documented that petitioner was seeing a psychologist on a regular basis while in college. Pet. Ex. 12 at 1. Petitioner "apparently had a [history] of hypochondriasis coming to psychologist with all sorts of somatic complaints/fears. Following graduation, [petitioner] alienated all of his friends on Crew team living on friends couches not taking care of his responsibilities, parents brought him home" and "[t]ook his passport away [because] [petitioner] was planning on going to India to get stem cell replacements." Id. In past two weeks, petitioner "[h]as been isolative, physically aggressive with parents, talking about governments following him, [and] planes following him from government tracking him." Id. He has also "woken his parents up for past 5 nights, has been up late at night, goal directed activity blogging, knocking on neighbors[']s doors [and] [a]sking family friends for money trying to invest in 'bitcom.'" Id.

Under psychiatric history, Dr. Hoffnung noted this was petitioner's first psychiatric admission, petitioner had been seeing Dr. Corrado during college, petitioner had a suicide attempt in 2005, and petitioner had been receiving Lexapro from his primary care physician Dr. Bienenstock. Pet. Ex. 12 at 1. Family history consisted of a maternal grandmother who was suicidal and institutionalized. Id. at 2. Petitioner had been living at home with his parents for the past two years. Id. Mental status exam showed petitioner was alert to person and place; he appeared clean and unkempt; his behavior and speech were within normal limits; his mood was "great;" he had a constricted and inappropriate range of affect and euphoric quality of affect; his thoughts were goal directed; his thought content included "[d]elusions, [i]deas of reference[,] [petitioner] believe[d] he has special power of telepathy;" he had no perceptional disturbances; his memory was intact; he had poor insight and judgment; and he was not suicidal. Id. Petitioner "require[d] Hospitalization for safety" but was not suicidal or homicidal and had good behavioral control. Id. at 3.

Dr. Hoffnung summarized that petitioner's illness had a "gradual onset" that "start[ed] with somatic preoccupation while in college, with recent period of decompensation, social isolation, aggressiveness towards parents, [presents] with euphoric/manic symptoms, referential and paranoid delusions." Pet. Ex. 12 at 3. Petitioner was admitted and given Risperdal,[14]

[13] There is no allegation to suggest that petitioner's parents were incapacitated and unable to bring a claim on behalf of petitioner while he was a minor.

[14] Risperdal is a trademark for risperidone, an antipsychotic agent. Risperdal, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=43964 (last visited Mar. 11, 2021); Risperidone, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=43965 (last visited Mar. 11, 2021).

Lexapro, Zyprexa,[15] Haldol,[16] Ativan, and Benadryl. Id. at 3-4.

A psychosocial assessment conducted on October 8, 2013 included information taken from petitioner's mother and noted petitioner was living at home with his parents. Pet. Ex. 12 at 5. Petitioner did not have an advance directive or a health care proxy. Id. at 7.

Petitioner was discharged on October 21, 2013 with diagnosis of schizoaffective disorder and bipolar disorder. Pet. Ex. 12 at 10, 12. Over his stay, "[petitioner] became more organized in thought and appeared less preoccupied by somatic concerns. [Petitioner] reported that lithium had helped 'even' his mood and that he planned to continue taking it after discharge." Id. at 10. Petitioner also spoke more about his upbringing and was given extensive psychotherapy and family meeting time. Id. at 10-11. By the end of his stay, petitioner's anxiety improved and his manic and psychotic symptoms resolved. Id. at 11. He "was eating and sleeping well, was attending groups regularly, and [was] motivated to continue learning about Bipolar Disorder." Id. Petitioner agreed to take the lithium (Lithobid),[17] but was "hesitant to initiate Seroquel[18] and Lamictal (or any other medications at this time)." Id. "[Petitioner] and [his] parents actively participated in treatment plan and all three agree[d] to [] treatment plan." Id. Petitioner was instructed to call his psychiatrist "if he experiences overwhelming depression, anxiety, manic symptoms[,] or psychotic symptoms." Id. His discharge medication included Lithobid. Id.

On December 31, 2013, petitioner was admitted to Adult Partial Hospital Program ("PHP"). Pet. Ex. 12 at 14. Mental status exam found petitioner was anxious, depressed, and oriented to time, place, and person; his mood was "okay;" his thought form was circumstantial, overinclusive, and illogical; his thought content included delusions and somatic preoccupation; and he exhibited impaired memory, partial insight, and poor judgment. Id. at 19-20. Since his admission in October 2013, petitioner was seeing Dr. Christman, who referred petitioner to PHP

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[15] Zyprexa is a trademark for olanzapine, which is "used as an antipsychotic in the management of schizophrenia and for short-term treatment of manic episodes in bipolar disorder." Zyprexa, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=54214 (last visited Mar. 11, 2021); Olanzapine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=34838 (last visited Mar. 11, 2021).

[16] Haldol, or haloperidol, is an antipsychotic agent. Haloperidol, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=21358 (last visited Mar. 11, 2021).

[17] Lithobid, or lithium, is "used as a mood stabilizer in treatment of acute manic and hypomanic states in bipolar disorder." Lithium Carbonate, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=87087 (last visited Mar. 11, 2021).

[18] Seroquel, or quetiapine fumarate, is "used as an antipsychotic in the treatment of schizophrenia and other psychotic disorders." Seroquel, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=45511 (last visited Mar. 11, 2021); Quetiapine Fumarate, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=42593 (last visited Mar. 11, 2021).

for "continued psychotic symptoms and depressed mood." Id. He started petitioner on Ativan. Id. at 14. Other antipsychotics were trialed during his stay at PHP, but with each medication, petitioner "complained of vague side effects, not wanting to continue them." Id. On admission, he "reported symptoms of depression, anxiety, and residual symptoms of psychosis. He endorsed depressed mood, decreased concentration and focus, low energy, and anhedonia. He continued to be somatically preoccupied, delusional, and his thought process was disorganized, illogical, and irrational." Id. During his time at PHP, he "remained delusional, somatically preoccupied, complaining of depression and anxiety as well as impaired energy and concentration" and he was "focused on his medication regimen, complaining of side effects and . . . was taking more Ativan and Haldol than prescribed although he was requesting discontinuation of Haldol due to reported side effects." Id.

On January 10, 2014, petitioner requested to be taken to the emergency room and be admitted due to worsening of symptoms, and was therefore discharged from PHP and admitted to the hospital. Pet. Ex. 12 at 14. Under the PHP treatment outcome, petitioner was noted to be worse, symptomatically unstable, and functioning below baseline. Id. at 16.

Dr. Yankel Girshman conducted the initial assessment. Pet. Ex. 12 at 23. Petitioner's "parents [were] concerned for his safety, as he [was] becoming more disorganized at home, requiring help to shower and unable to take his medications [appropriately]." Id. Dr. Christman felt petitioner would benefit from inpatient psychiatric hospitalization and petitioner's parents did not feel safe bringing petitioner home. Id. Dr. Girshman noted petitioner was "unable to function" and was "acutely dangerous to himself." Id. Petitioner agreed to voluntary inpatient psychiatric admission. Id. Mental status exam found petitioner was alert in orientation; his activity and behavior were "[p]sychomotor retarded, [w]ithdrawn, [and] [s]leep disturbance;" he was depressed and withdrawn; he had delusions, somatic preoccupation, and poor insight and judgment. Id. at 24-25.

Petitioner was discharged on January 17, 2014 with a diagnosis of schizoaffective disorder. Pet. Ex. 12 at 31, 33. Petitioner was noted to have strong family support and was motivated for continued treatment and medication compliance. Id. at 32. Petitioner and his family agreed with discharge and found it safe for him to return home. Id. A long acting injectable ("LAI") antipsychotic was considered but not prescribed "because there [was] reasonable expectation that the [petitioner] [would] adhere to current antipsychotic medication." Id.

Petitioner was admitted to PHP on January 21, 2014, and "reported some improvements in his symptoms but continued to endorse depressed mood, anxiety, and residual symptoms of psychosis." Pet. Ex. 12 at 38. On admission, petitioner complained of side effects of difficulty breathing and gastrointestinal issues from his medication. Id. Petitioner reported he stopped taking his medication (Invega)[19] on his own the day before due to side effects. Id. at 35. Mental status exam on admission found petitioner was fully oriented and anxious, with an "okay" mood. Id. at 44. He also had somatic preoccupations, intact memory, partial insight, and fair judgment.

[19] Invega, or paliperidone, is used to treat schizophrenia and schizoaffective disorder. Invega, RxList, https://www.rxlist.com/invega-drug.htm (last reviewed on Oct. 22, 2020).

Id. During his stay, PHP staff spoke to petitioner's mother "on a regular basis to discuss [his] progress, status, treatment[,] and medication recommendations as well as discharge planning." Id. at 39. Petitioner was discharged from PHP on February 21, 2014 with a discharge diagnosis of schizoaffective disorder. Id. at 38, 41. Petitioner's medications on discharge included Trilafon,[20] Lexapro, Lithium, Ativan, and Cogentin. Id. at 39.

On October 21, 2014, petitioner saw Dr. Bienenstock. Pet. Ex. 4 at 4. Petitioner provided his history of present illness. He complained of "heart racing and edema of feet" and reported that he "has been under a psychiatrist's care for several months and has been on different antipsychotics." Id. His current medications included Clozaril (Clozapine),[21] Lexapro, and Lithium Carbonate. Id. Dr. Bienenstock documented that petitioner was "alert and in no acute distress." Id. Dr. Bienenstock noted petitioner was tachycardic and recommended he see his psychiatrist "to discuss decreasing Clozaril." Id. Petitioner indicated he was seeing his psychiatrist the following day and was instructed to follow up with Dr. Bienenstock after the visit. Id. The assessments were arrhythmia, bipolar disorder, anxiety and depression, and weight gain. Id. at 5.

Dr. Jennifer Pasternack, petitioner's psychiatrist, provided an undated statement on behalf of petitioner to aid him in obtaining health insurance. Pet. Ex. 13 at 1. She stated that petitioner was admitted to CooperRiss on a residential care basis and later on a day patient care basis from January 8, 2015 to May 15, 2016. Pet. Ex. 13 at 1. Dr. Pasternack wrote petitioner suffers from schizoaffective disorder with paranoia. Id. She added that "[petitioner's] conditions caused him to have anxiety, depression, paranoia, psychosis, and poor memory/concentration." Id.

On September 29, 2016, petitioner filed a claim for supplemental security income ("SSI") benefits, which was approved on December 21, 2016. Pet. Ex. 16 at 1. The SSA found that as of September 2016, petitioner "met all the rules to be eligible for SSI based on being disabled." Id. The diagnosis that disability was based upon was not provided.[22]

On December 21, 2016, petitioner saw Nurse Practitioner, Claire Widen, for a follow up on his obstructive sleep apnea syndrome. Pet. Ex. 15 at 1. On exam, Ms. Widen noted petitioner was in "no apparent distress" and that he was alert and was oriented to time, person, and place. Id. at 3.

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[20] Trilafon, a perphenazine, is used "as an antipsychotic" and "in the treatment of anxiety associated with depression." Trilafon, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=51065 (last visited Mar. 11, 2021); Perphenazine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=38157 (last visited Mar. 11, 2021).

[21] Clozapine is "a sedative and antipsychotic agent." Clozapine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=10186 (last visited Mar. 11, 2021).

[22] Petitioner filed only the first page of the SSA's notice of award.

Psychiatric Nurse Practitioner, Lee Anne Horn completed a medical source statement for petitioner on May 17, 2018. Pet. Ex. 17 at 1-3. In her opinion, petitioner's abilities to perform certain activities or tasks had been impaired by his condition since "2012 through indefinite due to chronic relapsing/remitting nature of illness." Id. at 3. In a letter dated May 18, 2018, Ms. Horn noted that she began seeing petitioner for psychiatric medication management on December 28, 2016. Id. at 4. She added that "[petitioner] had a psychiatric history dating back to at least 2005." Id. Petitioner struggles with psychosis, anxiety, paranoia, and a panic disorder. Id. "While [petitioner] is able to complete job tasks and engage effectively," Ms. Horn found it "unlikely that [petitioner] would be able to tolerate a full time work schedule without exacerbating psychiatric symptoms." Id. at 5. Ms. Horn agreed with petitioner's diagnosis of schizoaffective disorder, bipolar type, and opined that "this diagnosis is permanent." Id. at 4-5.

In a letter dated July 12, 2018, Dr. Chris Mulchay wrote that he saw petitioner in therapy sessions from January 2015 to September 2015 and again starting in November 2016. Pet. Ex. 18 at 1. Dr. Mulchay did not opine as to onset of petitioner's condition in his letter.

On August 27, 2018, petitioner's claim for period of disability and disability insurance benefits was approved. Pet. Ex. 19 at 1-2. After a hearing on August 1, 2018, where petitioner appeared and testified, the administrative judge found petitioner "ha[d] not engaged in substantial gainful activity since October 1, 2013, the amended alleged onset date." Id. at 2. The judge concluded that petitioner has schizoaffective disorder and "has been under a disability as defined in the Social Security Act since October 1, 2013." Id. at 2, 6.

On December 13, 2018, petitioner saw Dr. Sukhbir Singh Guram, and orthopedic surgeon, for chronic low back pain. Pet. Ex. 44 at 6.[23] Petitioner reported being "on disability due to underlying psychiatric issues including anxiety and bipolar disorder."[24] Id. Past medical history included anxiety, bipolar disorder, and depression. Id. at 7. Petitioner was on Clozapine, Lexapro, and Lithium. Id. Dr. Guram's record from this visit reveals that he took a thorough history and performed a physical examination. There is no indication, based on the record, that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

On January 3, 2020, petitioner saw orthopedic Physician Assistant, Richard George Cardillo, for low back pain. Pet. Ex. 44 at 2. Under review of symptoms, petitioner was noted to have "[n]o depression, anxiety, or other mood changes." Id. at 3. Current medications included Clozapine (Clozaril and Fazaclo), Lexapro, and Lithium (Lithobid). Id. On examination, petitioner was alert, oriented, and in no acute distress. Id. at 4.

[23] This exhibit does not contain an exhibit number, but according to petitioner's record, he refers to this exhibit as Exhibit 44, and thus, the undersigned will do the same. See ECF Nos. 19, 21.

[24] The same record also notes petitioner was working Ingles Grocery. See also Pet. Ex. 34.

C. Petitioner's Statements and Letters

Petitioner alleged that "most if not all [of his vaccines] had a negative [e]ffect contributing to [his] off-Table injury of mental illness." Pet. Mot. to Proceed at 11. Petitioner explained that "the DPT vaccines caused a chain reaction in [his] body, physically, mentally, psychologically, and consciously" and he "was plagued with routine mental distress and illness," including "headaches, throat and earaches, upset stomachs, chills, pains, stiffness, fevers, coughs, allergies, episodes, swallowing difficulty, [and] acne." Pet. Ex. 39 at 1.

From childhood into adulthood, petitioner alleged that he was depressed and anxious. Pet. Mot. to Proceed at 14-15. Petitioner explained that he had various speech, learning, concentration, and disciplinary issues and difficulties growing up. Pet. Ex. 37 at 1. For support, he noted his lack of good grades, misbehavior in and out of school, and how he had to change schools growing up. Pet. Mot. to Proceed at 15. During this time, he "had the proclivity to make unsound decisions," he often felt depressed, and he had "irrational behaviors and thoughts." Pet. Ex. 39 at 2.

Petitioner alleged that his condition worsened in college. Pet. Ex. 39 at 3. "Anxiety and depression were a constant presence, continuing to build pressure, year after year since [his] vaccination[s], as [his] internal conditions continued to deteriorate." Id. at 4. Starting in 2006, while in college, "[his] health really started to deteriorate, as seen by [his] college health records." Pet. Mot. to Proceed at 15 (citing Pet. Ex. 5). He averred that "[his] depression and anxiety plagued [his] experience in and out of school." Id. He "wrestled with chronic illness and inflammation throughout [his] academic, sporting, and professional career." Pet. Ex. 37 at 1. "Around 2012[,] [he] was unable to function anymore on [his] own and was quite incapacitated. [He] left [his] work in San Francisco and moved home to New York to get help." Pet. Ex. 39 at 5.

Petitioner stated he "had a psychotic break and required involuntary hospitalization" where "[he] was diagnosed with Schizoaffective and Bipolar disorder."[25] Pet. Ex. 39 at 5-6. For the next two years, he worked with Dr. Christman to get on the right medications, which are Clozapine, Lexapro, and Lithium. Id. at 5. He averred that he "was practically bedridden for two plus years," but is now on the road to recovery. Id. As of February 1, 2020, petitioner was still suffering from mental illness and required medication and therapy, but his support system, including family, friends, teachers, and doctors, has helped him through his journey. Id. at 5-6.

Petitioner argued that he was a minor at vaccination, and his parents' consent to vaccination was not informed because they were not told "all the facts[] and real dangers." Pet. Mot. to Proceed at 14. "Given the lack of safety with these vaccines, [he is] sure [his] parents would not have approved." Id. Additionally, he alleged that his parents did not know about the Vaccine Program. Id.

[25] Petitioner did not specify the date in which this occurred, but he appears to be referencing his psychiatric admission in October 2013. See Pet. Ex. 12 at 1, 12.

D. Petitioner's Expert Report from Judy A. Mikovits, Ph.D. and Francis W. Ruscetti, Ph.D.[26]

Drs. Mikovits and Ruscetti are "career translational research and development PhD Scientists." Pet. Ex. 49 at 1. Dr. Mikovits received her B.A. in Biology with a specialization in Biochemistry from the University of Virginia and her Ph.D. in Biochemistry and Molecular Biology from the George Washington University. ECF No. 24-9 at 3.[27] Dr. Mikovits completed a post-doctoral fellowship in molecular virology at the National Cancer Institute from 1992 to 1994. Id. Since then, she has worked at various laboratories in varying roles. Id. at 1-2. Dr. Ruscetti received her B.S. in Biology from Boston University and her Ph.D. in Microbiology from the University of Pittsburgh. ECF No. 24-2 at 1.[28] Since 1972, Dr. Ruscetti has worked as a research instructor, cell biologist, cancer expert, investigator, and more. Id. Neither Dr. Mikovits nor Dr. Rusetti are medical doctors. Neither appeared to have knowledge, training, or experience treating or researching patients who had mental illnesses.

Drs. Mikovits and Ruscetti opined that petitioner's five DPT, five Polio, and two MMR vaccinations "administered from the time he was [six] weeks of age and his [fifth] birthday caused repeated and sustained neuroinflammation (encephalopathy/Encephalitis) and neuroimmune disease development which resulted ultimately in a diagnosis of Schizoaffective and Bipolar disorder." Pet. Ex. 49 at 1. They added that petitioner "experienced and demonstrated" symptoms "which plagued him throughout his life exacerbated by each inoculation." Id. at 6. They did not opine as to onset of petitioner's mental health conditions, diagnoses, symptoms, or illness except to state they plagued him throughout his life.

III. PARTIES' CONTENTIONS

A. Petitioner's Contentions Regarding Onset

Petitioner filed multiple filings with inconsistent statements as to "the first symptom or manifestation of onset" of his alleged vaccine-related illnesses. § 16(a)(2). First, in his petition, petitioner alleged that his "illness, symptoms[,] and chronic condition have lasted since [his] first DPT vaccine administration on June 29, 1987 and have compounded since then." Petition at 6. Petitioner alleged that he sustained injuries, including "Autoimmune Disorders, psychic injury and trauma, loss of wages and productivity, excessive medical expenses, decreased quality of life, collateral damage, and challenge to fulfilling all God-given potential," resulting from adverse effects of DPT vaccinations received on June 29, 1987, September 1, 1987, January 15, 1988, July 13, 1990, and July 9, 1991. Id. at 1.

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[26] The undersigned has reviewed the expert report and all supporting medical literature, but only summarizes those arguments and statements pertinent to this Decision.

[27] Because this document does not contain an exhibit number, the undersigned will refer to this document by the Docket Entry number for clarity.

[28] Because this document does not contain an exhibit number, the undersigned will refer to this document by the Docket Entry number for clarity.

Next, petitioner, in a letter addressed to the Chief Special Master, alleged that the "DPT and other vaccines . . . resulted in compounding damages throughout [his] life." Pet. Ex. 37 at 1. For support, he explained that he had various speech, learning, concentration, and disciplinary issues and difficulties growing up, and he "wrestled with chronic illness and inflammation throughout [his] academic, sporting, and professional career." Id.

Third, in petitioner's response to the undersigned's order to show cause, petitioner alleged that his medical records show he "was healthy before [his] DPT vaccines, and that as soon as they were administered and after, [he] experienced negative reactions." Pet. Ex. 39 at 1. He listed and described various instances in his childhood where he was sick, needed to be taken to the hospital, and struggled in school. Id. at 1-2. And, in 2005, while in college, he explained that his condition continued to be unstable and worsen, and he noted various doctor's visits over the following years. Id. at 3-6.

Fourth, in petitioner's motion to proceed, petitioner did not specifically address when the onset of his alleged vaccine-related injury occurred, but he discussed issues with development from childhood to adulthood and alleged that "most if not all [of his vaccines] had a negative [e]ffect contributing to [his] off-Table injury of mental illness." Pet. Mot. to Proceed at 11, 14-15. Petitioner stated, "[t]he off-Table injury [he is] claiming is twofold: 1. Separation from the Holy Spirit and God 2. Depression & anxiety, both (1 and 2) contributing to mental illness from inception of vaccines." Id. at 11.

Lastly, petitioner filed a response, entitled "Additional Evidence that Claim Isn't Time-Barred," where he alleged that the onset of his symptoms began on October 1, 2013, the date in which the SSA found him disabled. Pet. Response at 2. Specifically, petitioner stated "[t]he [DPT] vaccines given on July 13, 1990 and July 9, 1991 caused petitioner's schizoaffective disorder and severe bipolar disorder" and he has been mentally incapacitated since October 1, 2013. Id. "Petitioner agree[d] that up until October 1, 2013[,] petitioner's mental health issues did not raise to a level of severity where petitioner, nor his parents during his minority years, could not make a rational decision about his health." Id. at 3. Since October 1, 2013, "petitioner has been unable to diligently handle his affairs." Id.

B. Petitioner's Contentions Regarding Equitable Tolling

Petitioner argued equitable tolling should apply to his claim because he has "been in a fog for a long time" and is "starting to awaken." Pet. Ex. 37 at 2. Petitioner specifically requested the undersigned use "extraordinary circumstances, equitable tolling based upon mental illness, and . . . stop-clock approach." Pet. Ex. 39 at 1 (internal quotation marks omitted).

In petitioner's response entitled "Additional Evidence that Claim Isn't Time-Barred," petitioner alleged he has been mentally incapacitated since October 1, 2013, "the date that the [SSA] ruled him disabled," and "the 36-month statute of limitations should be equitably tolled due to mental incapacity." Pet. Response at 2. Quoting K.G. v. Secretary of Health & Human Services, petitioner explained that his "failure to file was the direct result of a mental illness or disability that rendered [him] incapable of rational thought, incapable of deliberate decision

making, incapable of handling [his] own affairs, or unable to function in society." Id. at 3 (quoting K.G. v. Sec'y of Health & Hum. Servs., 951 F.3d 1375, 1381 (Fed. Cir. 2020)). Relying on K.G. and Hodge, and based on his expert report, medical records, and the SSA's decision, petitioner argued that he has shown extraordinary circumstances. Id. at 6 (citing K.G., 951 F.3d at 1379-81; Hodge v. Sec'y of Health & Hum. Servs., No. 09-453V, 2015 WL 9685916, at *8 (Fed. Cl. Spec. Mstr. Dec. 21, 2015)).

Petitioner argued that "for [his] claim to be equitably tolled, the clock must be stopped at least three years, two months, and twenty-six days due to his mental incapacity in order to fall within the 36-month statute of limitations." Pet. Response at 7. Petitioner explained that he filed his claim on December 27, 2019 and the onset of his symptoms were October 1, 2013. Id. Because the SSA rendered him disabled by his schizoaffective disorder since October 1, 2013, the "clock" should stop "during the entire period of October 1, 2013 to December 27, 2019." Id. Additionally, petitioner alleged Dr. Mulchay found "petitioner was mentally incapacitated from January 2015 to at least July 2018[,] which amounts to three years and six months, a length of time well over the requirement needed to fall within the 36-month timeframe."[29] Id.

C. Respondent's Contentions Regarding Onset

Respondent argued that petitioner's alleged injuries caused by DPT vaccines administered on June 29, 1987, September 1, 1987, and January 15, 1988 are governed by § 16(a)(1) and are time-barred. Resp. Mot. at 3. Under that section, petitioner had 28 months after October 1, 1988 to file his petition. Id. Respondent argued that because petitioner did not file his petition within 28 months after October 1, 1988, these claims are time-barred. Id.

With regard to petitioner's alleged injuries caused by DPT vaccines administered on July 13, 1990 and July 9, 1991, respondent argued these claims are governed by § 16(a)(2) and are also time-barred. Resp. Mot. at 3. Under that section, petitioner's claim must have been filed within 36 months of the first symptom or manifestation of onset of the alleged vaccine-related injury. Respondent argued petitioner did not file his claim within 36 months of onset, and thus, his claim is time-barred. Id.; Resp. Reply at 5.

For support, respondent cites to an assessment performed on October 4, 2013 that stated petitioner had a "history of gradual onset of illness starting with somatic preoccupation while in college." Resp. Reply at 3 (quoting Pet. Ex. 12 at 3). Because petitioner graduated from college in May 2010, onset of his illness would be more than 41 months prior to this time. Id. Respondent argued that for years prior to October 2013, petitioner's records show symptoms of anxiety, depression, and poor memory and concentration, which Dr. Pasternack, petitioner's psychiatrist, attributed to petitioner's schizoaffective disorder. Id. at 3-4. Respondent added that petitioner admitted in several filings that his symptoms pre-dated October 2013. Id. at 4.

Respondent explained that petitioner's alleged mental incapacity began no earlier than October 2013. Resp. Mot. at 4-5; Resp. Reply at 5. Because the records document petitioner

[29] Dr. Mulchay's letter does not state that petitioner was mentally incapacitated from January 2015 to at least July 2018. See Pet. Ex. 18.

was experiencing symptoms of his illness for more than 36 months prior to the start of his alleged mental incapacity in October 2013, his claim is time-barred. Resp. Reply at 5. Thus, this case should be dismissed because it was filed outside the Vaccine Act's statute of limitations. Id.

D. Respondent's Contentions Regarding Equitable Tolling

Citing K.G., respondent maintained that although petitioner contended equitable tolling should apply, "[t]here is no evidence that petitioner was incapable of rational thought, incapable to deliberative decision making, incapable of handling his own affairs, or unable to function in society during the decades-long period between the supposed onset of the alleged injuries and October 2013." Resp. Mot. at 4-5 (citing K.G., 951 F.3d at 1380-82). For support, respondent pointed to petitioner's records showing petitioner "successfully completed high school and college while simultaneously participating in competitive athletics, and held various jobs." Id. at 5. Respondent also noted that petitioner did not address nor demonstrate how he has been diligently pursuing his rights, a requirement under Pace v. DiGuglielmo, 544 U.S. 408, 418 (2005). Id. at 5 n.2.

Respondent argued that the statute of limitations expired before petitioner's alleged incapacitation on October 1, 2013 because petitioner's symptoms were present for more than 36 months prior to that date. Resp. Reply at 2-3, 5. Thus, the question of whether equitable tolling should be applied is irrelevant. Id. at 2-3.

IV. LEGAL FRAMEWORK

A. Vaccine Act Statute of Limitations

Section 16(a)(1) of the Vaccine Act, which governs claims resulting from vaccines administered before October 1, 1988, states,

> if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after October 1, 1988, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine.

§ 16(a)(1). Thus, for claims resulting from vaccines administered before October 1, 1988, a petition must be filed within 28 months after October 1, 1988 (i.e., before February 1, 1991) and the first symptom or manifestation of onset must have been within 36 months of vaccination.

Section 16(a)(2) of the Vaccine Act governs claims resulting from vaccines administered after October 1, 1988, and reads,

> if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first

> symptom or manifestation of onset or of the significant aggravation of such injury.

§ 16(a)(2). Therefore, claims resulting from vaccines administered after October 1, 1988 must be filed within 36 months of the first symptom or manifestation of onset of the alleged vaccine-related injury. The statute of limitations begins to run from the onset of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis. Carson v. Sec'y of Health & Hum. Servs., 727 F.3d 1365, 1369 (Fed. Cir. 2013). Special masters have appropriately dismissed cases that were filed outside the limitations period, even by a single day or two. See, e.g., Spohn v. Sec'y of Health & Hum. Servs., No. 95-0460V, 1996 WL 532610 (Fed. Cl. Spec. Mstr. Sept. 5, 1996) (dismissing case filed one day beyond the 36-month limitations period), aff'd, 132 F.3d 52 (Fed. Cir. 1997); Cakir v. Sec'y of Health & Hum. Servs., No. 15-1474V, 2018 WL 4499835, at *4 (Fed. Cl. Spec. Mstr. July 12, 2018).

B. Doctrine of Equitable Tolling

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act claims in limited circumstances. See Cloer v. Sec'y of Health & Hum. Servs., 654 F.3d 1322, 1340-41 (Fed. Cir. 2011). The Federal Circuit determined equitable tolling on the basis of mental incompetence is available in Vaccine Act cases. K.G., 951 F.3d at 1381. However, lack of knowledge of an actionable claim is not a basis for equitable tolling. Id. at 1380 (citing Cloer, 654 F.3d at 1344-45).

Section 16(a)(1) is a statute of repose, rather than a statute of limitations, and thus, the statutory deadline under this section may not be tolled for equitable reasons. See Lombardo v. Sec'y of Health & Hum. Servs., 34 Fed. Cl. 21, 24 (2015); Weddel v. Sec'y of Health & Hum. Servs., 100 F.3d 929, 932 (Fed. Cir. 1996). Section 16(a)(2), on the other hand, allows courts to use equitable tolling "sparingly" and in "extraordinary circumstances." Cloer, 654 F.3d at 1344-45 (quoting Pace, 544 U.S. at 418; Irwin v. Dep't of Veteran Affs., 498 U.S. 89, 96 (1990)).

To establish that equitable tolling of a statute of limitations is appropriate, a claimant must prove (1) he pursued his rights diligently and (2) an extraordinary circumstance prevented him from timely filing the claim. K.G., 951 F.3d at 1379 (citing Menominee Indian Tribe v. United States, 136 S. Ct. 750, 755 (2016). The Federal Circuit determined "the proper analysis of equitable tolling based on mental incapacity in the Vaccine Act context must consider both extraordinary circumstances and diligence." Id. at 1381. All relevant facts and circumstances must be considered when determining whether a claimant pursued his rights diligently. Id. at 1382. "It is possible, for instance, that a reasonable amount of diligence for an individual with memory loss or hallucinations would equate to no diligence for an able-minded individual." Id. Additionally, "[a] claimant need only establish diligence during the period of extraordinary circumstances to meet this test." Id. (citing Checo v. Shinseki, 748 F.3d 1373, 1380 (Fed. Cir. 2014)).

To show extraordinary circumstances, "a Vaccine Act claimant must show that [his] failure to file was the direct result of a mental illness or disability that rendered [him] incapable of rational thought, incapable of deliberate decision making, incapable of handling [his] own

affairs, or unable to function in society." K.G., 951 F.3d at 1381. However, "[a] medical diagnosis alone or vague assertions of mental problems are insufficient" to establish extraordinary circumstances. Id. at 1381-82.

C. Standards for Adjudication

1. Motion to Dismiss

Although the Vaccine Act and the Vaccine Rules contemplate case dispositive motions, the dismissal procedures included within the Vaccine Rules do not specifically include a mechanism for a motion to dismiss. See §§ 12(d)(2)(C)-(D); Vaccine Rule 8(d); Vaccine Rule 21. However, Vaccine Rule 1 provides that for any matter not specifically addressed by the Vaccine Rules, the special master may regulate applicable practice consistent with the rules and the purpose of the Vaccine Act. Vaccine Rule 1(b). Vaccine Rule 1 also provides that the Rules of the Court of Federal Claims ("RCFC") may apply to the extent they are consistent with the Vaccine Rules. Vaccine Rule 1(c).

Accordingly, there is a well-established practice of special masters entertaining motions to dismiss in the context of RCFC 12(b)(6), which allows the defense of "failure to state a claim upon which relief can be granted" to be presented via motion. See, e.g., Herren v. Sec'y of Health & Hum. Servs., No. 13-1000V, 2014 WL 3889070 (Fed. Cl. Spec. Mstr. July 18, 2014); Bass v. Sec'y of Health & Hum. Servs., No. 12-135V, 2012 WL 3031505 (Fed. Cl. Spec. Mstr. June 22, 2012); Guilliams v. Sec'y of Health & Hum. Servs., No. 11-716V, 2012 WL 1145003 (Fed. Cl. Spec. Mstr. Mar. 14, 2012); Warfle v. Sec'y of Health & Hum. Servs., No. 05-1399V, 2007 WL 760508 (Fed. Cl. Spec. Mstr. Feb. 22, 2007).

Under RCFC 12(b)(6), a case should be dismissed "when the facts asserted by the claimant do not entitle him to a legal remedy." Extreme Coatings, Inc. v. United States, 109 Fed. Cl. 450, 453 (2013) (quoting Lindsay v. United States, 295 F.3d 1252, 1257 (Fed. Cir. 2002)). In considering a motion to dismiss under RCFC 12(b)(6), allegations must be construed favorably to the pleader. Id. (citing Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). However, the pleading must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Golden v. United States, 137 Fed. Cl. 155, 169 (2018) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)); see also Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007).

"To determine whether a complaint states a plausible claim for relief, the court must engage in a context-specific analysis and 'draw on its judicial experience and common sense.'" Golden, 137 Fed. Cl. at 169 (quoting Iqbal, 556 U.S. at 679). However, "Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations." Neitzke v. Williams, 490 U.S. 319, 327 (1989). Nonetheless, on a motion to dismiss, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986). In assessing motions to dismiss in the Vaccine Program, special masters have concluded that they "need only assess whether the petitioner could meet the Act's requirements and prevail, drawing all inferences from the available evidence in petitioner's favor." Herren, 2014 WL 3889070, at *2; see also Warfle, 2007 WL 760508, at *2.

2. Summary Judgment

As in Warfle and other motions to dismiss decided in this Program, the Vaccine rules allow for a special master to decide a case on summary judgment. See Jay v. Sec'y of Health & Hum. Servs., 998 F.2d 70, 82-83 (Fed. Cir. 1992). Pursuant to Vaccine Rule 8, "[t]he special master may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in RCFC 56 will apply." Vaccine Rule 8(d). Congress specifically mandated that the Vaccine Rules "include the opportunity for summary judgment," to decide "[i]ssues of statutory interpretation and other matters of law." § 12(d)(2)(C); Santa Fe Pacific R. Co. v. United States, 294 F.3d 1336, 1340 (Fed. Cir. 2002).

Summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." RCFC 56(a). A dispute is genuine if "the evidence is such that a reasonable [fact finder] could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc. v. United States, 477 U.S. 242, 248 (1986). A fact is material if it "might affect the outcome of the suit under the governing law." Id. The moving party "bears the [burden] of . . . demonstrat[ing] the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The burden then shifts to the nonmoving party to "set forth specific facts showing that there is a genuine issue for trial." Anderson, 477 U.S. at 256. A showing of "mere denials or conclusory statements [is] not sufficient" to demonstrate genuine disputes. Mingus Constructors, Inc. v. United States, 812 F.2d 1387, 1390-91 (Fed. Cir. 1987).

3. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." In re Winship, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

A special master must consider any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). Despite the weight afforded medical records, special

masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is decided relative to the injury[,]" determining facts relating to the claimed injury can be significant in a case like this, where petitioner has an evolving course of symptoms, resulting in a diagnosis years later. Id. Thus, the undersigned must first address whether petitioner has established, by a preponderance of the evidence, that he suffers from an autoimmune illness and/or a mental health illness.

V. DISCUSSION

A. Claims Under § 16(a)

1. Claims Under § 16(a)(1)

In his petition, petitioner alleged that he suffered adverse effects from DPT vaccines administered on June 29, 1987, September 1, 1987, and January 15, 1988. Because these three vaccines were administered before October 1, 1988, any claims arising from these vaccines are governed by § 16(a)(1).

Under § 16(a)(1), a petition cannot be filed (1) "after the expiration of 28 months after October 1, 1988" and (2) "if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine." § 16(a)(1).

Petitioner had 28 months after October 1, 1988, or until February 1, 1991, to file a claim resulting from the vaccines he received in 1987 and 1988. Because his petition was not filed until December 27, 2019, petitioner's claims for injuries resulting from these vaccines, and any other vaccines administered to petitioner before October 1, 1988, are time-barred.

The undersigned also finds petitioner's "first symptom or manifestation of onset . . . occurred more than 36 months after" the vaccinations petitioner received before October 1, 1988, as described in more detail below. Thus, because the undersigned finds petitioner's onset for his alleged vaccine-related injuries was more than 36 months after the vaccinations, petitioner's claims for injuries resulting from vaccines administered before October 1, 1988 remain time-barred.

2. Claims Under § 16(a)(2)

a. Alleged Injuries in Petition

Petitioner also alleged that he sustained injuries, including "Autoimmune Disorders, psychic injury and trauma, loss of wages and productivity, excessive medical expenses, decreased quality of life, collateral damage, and challenge to fulfilling all God-given potential," resulting from adverse effects of DPT vaccinations received on July 13, 1990 and July 9, 1991.[30] Petition at 1.

First, with regard to "Autoimmune Disorders," the petitioner failed to identify or specify what he meant by the allegation. On February 4, 2013, under past medical history, Dr. LePine documented "[a]utoimmune [d]isease possible." Pet. Ex. 11 at 3. However, this note was based on petitioner's own statements and was not a diagnosis of an autoimmune disease or disorder. Additionally, Dr. LePine noted "neg[ative] autoimmune markers." Id. References to a "possible" autoimmune disorder or disease is not evidence of a diagnosis of an autoimmune disorder.[31]

There are references to Celiac disease[32] in some of petitioner's medical records; however, petitioner was never diagnosed with Celiac disease. On December 8, 2011, petitioner underwent a biopsy to test for the illness. Pet. Ex. 7 at 6. "In the appropriate clinical context, the findings [were] consistent with celiac disease" but because of the presence of *H. pylori*, "correlation with clinical and serological parameters [was] recommended to determine whether the findings in the duodenum represent celiac disease." Id. On January 13, 2012, petitioner was noted to have been diagnosed with gastritis with *H. pylori* and had a normal celiac panel on December 8, 2011. Pet. Ex. 6 at 22. Petitioner was positive for human leukocyte antigen (HLA) DQ2 on January 30, 2012, but "[t]hese antigens are not diagnostic of celiac disease." Pet. Ex. 7 at 5. The remaining records that mention celiac disease note that it is "possible," based on petitioner's report, and/or "not verified." See Pet. Ex. 11 at 3; Pet. Ex. 12 at 1, 17; Pet. Ex. 18 at 1 ("[Petitioner] has

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[30] Because the undersigned already determined that any claims arising from vaccines administered prior to October 1, 1988 are governed by § 16(a)(1) and are time-barred, these vaccines are not addressed in this section.

[31] Opinions based on possibilities are insufficient to establish causation. See, e.g., Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008); Burns v. Sec'y of Health & Hum. Servs., No. 90-953V, 1992 WL 365410, at *6 (Fed. Cl. Spec. Mstr. Nov. 6, 1992), aff'd, 3 F.3d 415 (Fed. Cir. 1993); LaCour v. Sec'y of Health & Hum. Servs., No. 90-316V, 1991 WL 66579, at *5 (Fed. Cl. Spec. Mstr. Apr. 15, 1991) ("Expert medical testimony which merely expresses the possibility—not the probability—of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred.").

[32] Celiac disease is "an autoimmune malabsorption syndrome precipitated by ingestion of gluten-containing foods." Celiac Disease, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=70171 (last visited Mar. 11, 2021).

reported an unverified history of Celiac disease and chronic fatigue syndrome."). While the records evidence a work-up for Celiac disease, there is no evidence that petitioner was ever diagnosed with the condition.

Drs. Mikovits and Ruscetti did not opine as to onset of any autoimmune disorder.[33]

There is no evidence in petitioner's medical records establishing that he was diagnosed with an autoimmune disorder. Thus, the undersigned finds that petitioner has failed to provide preponderant evidence which supports his position as to the statute of limitations with regard to any autoimmune disorder.[34]

b. Mental Illness

Petitioner also alleged injuries of "psychic injury and trauma, loss of wages and productivity, excessive medical expenses, decreased quality of life, collateral damage, and challenge to fulfilling all God-given potential."[35] While these alleged injuries are vague, they appear to be related to petitioner's mental health issues.[36]

In his motion to proceed, petitioner alleged that "most if not all [of his vaccines] had a negative [e]ffect contributing to [his] off-Table injury of mental illness." Pet. Mot. to Proceed at 11, 14-15. Specifically, "[t]he off-Table injury [he is] claiming is twofold: 1. Separation from the Holy Spirit and God 2. Depression & anxiety, both (1 and 2) contributing to mental illness from inception of vaccines." Id. at 11. And, in his response, petitioner alleged "[t]he [DPT] vaccines given on July 13, 1990 and July 9, 1991 caused petitioner's schizoaffective disorder and severe bipolar disorder." Pet. Response at 2.

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[33] The undersigned and other special masters have previously found the opinions of Drs. Mikovits and Ruscetti deficient. See, e.g., Deisher v. Sec'y of Health & Hum. Servs., No. 17-294V, 2019 WL 1870737, at *11-15 (Fed. Cl. Spec. Mstr. Apr. 1, 2019); Rogero v. Sec'y of Health & Hum. Servs., No. 11-770V, 2017 WL 4277580, at *24 (Fed. Cl. Spec. Mstr. Sept. 1, 2017); McCabe v. Sec'y of Health & Hum. Servs., No. 13-570V, 2018 WL 3029175, at *14-18, *20-22, *32-33 (Fed. Cl. Spec. Mstr. May 17, 2018); Dominguez v. Sec'y of Health & Hum. Servs., No. 12-378V, 2018 WL 3028975, at *5-6 (Fed. Cl. Spec. Mstr. May 25, 2018); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at *37 n.69, *46-48 (Fed. Cl. Spec. Mstr. July 15, 2019). The undersigned has reviewed and considered the opinions of Drs. Mikovits and Ruscetti here, and finds they are not informative as to the legal issues presented.

[34] Even if petitioner were able to establish that he did have an autoimmune illness, he would not be able to recover for it for reasons explained in Section VI.B.

[35] With regard to "loss of wages and productivity, excessive medical expenses, decreased quality of life, [and] collateral damage," the undersigned finds these are best categorized items of compensation as opposed to alleged vaccine-related injuries.

[36] This is based on all of petitioner's filings, not just his petition.

Based upon a review of all of the evidence, the undersigned finds that the records support the alleged diagnosis of mental illness. The onset of petitioner's mental illness alleged as vaccine related began as early as 2005, but no later than October 2006, when Dr. Corrado diagnosed him with anxiety.

Petitioner's medical records show petitioner began experiencing mental health problems in 2005. Petitioner had a car accident that he later described as a suicide attempt in May 2005. He had a panic attack in September 2006. In October 2006, Dr. Corrado assessed petitioner with anxiety. From October 2006 to September 2009, petitioner saw Dr. Corrado numerous times for varying issues. Anxiety and/or depression, as well as related symptoms and issues, were mentioned in most of these records. Dr. Corrado encouraged petitioner to consider therapy or counseling multiple times to help with his anxiety. On February 27 and May 21, 2007, petitioner underwent mental health assessments verifying that petitioner attributed his issues back to the car accident in May 2005, and the panic attack in September 2006, and had since had "anxious worries about his body." Pet. Ex. 5 at 78; see also Pet. Ex. 5 at 62-63. At most of his visits since 2006, petitioner was noted to worry about potential health issues that he wanted to rule out before accepting that he had anxiety. All diagnostic tests were unremarkable, and no underlying medical issue was found.[37] On August 12, 2010, petitioner was prescribed Lexapro, which petitioner took most of 2010 to 2012. Petitioner was also on Ativan for part of 2010. During this time, petitioner was seeing a psychiatrist at Arlington Heights for his anxiety and depression.

Petitioner's treating physicians date the onset of petitioner's mental health issues between 2005 and 2006. Dr. LePine, in February 2013, noted petitioner had anxiety since 2006. Pet. Ex. 11 at 4. Dr. Hoffnung found petitioner's illness had a "gradual onset" that "start[ed] with somatic preoccupation while in college."[38] Pet. Ex. 12 at 3. Psychiatric Nurse Practitioner, Lee Anne Horn, noted that "[petitioner] had a psychiatric history dating back to at least 2005." Pet. Ex. 17 at 4.

Additionally, petitioner's own statements place the onset of his mental health condition back to college. Petitioner admitted his condition worsened in college, with "[a]nxiety and depression [as] a constant presence." Pet. Ex. 39 at 3-4. He averred that "[his] depression and anxiety plagued [his] experience in and out of school." Pet. Mot. to Proceed at 15.

Drs. Mikovits and Ruscetti did not opine as to onset of petitioner's mental health conditions, symptoms, or illness except to state they plagued him throughout his life.[39]

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[37] Although some records document that various medical conditions may be "possible," petitioner was never actually diagnosed with these conditions.

[38] Petitioner attended college from 2005 to 2010.

[39] Again, the undersigned does not find their opinions informative as to the legal issues presented.

In summary, the records establish that petitioner's anxiety and depression were initially documented as occurring as early as 2005 but no later than October 2006, when Dr. Corrado diagnosed him with anxiety. In order to timely file his claim prior to the expiration of the statute of limitations, and using the later time of October 2006, the petitioner's claim for vaccine-related mental illness should have been filed no later than October 2009. The petition was filed on December 27, 2019, more than ten years after the applicable statute of limitations period. The undersigned finds petitioner filed his petition alleging vaccine-related mental health issues more than "36 months after the date of the occurrence of the first symptom or manifestation of onset," and therefore, it is time barred. § 16(a)(2).

B. Equitable Tolling

1. Onset of Petitioner's Mental Incompetence

As described above, to establish that equitable tolling is appropriate, a petitioner must prove that (1) he pursued his rights diligently and (2) an extraordinary circumstance prevented him from timely filing the claim. K.G., 951 F.3d at 1379. To show extraordinary circumstances, "a Vaccine Act claimant must show that [his] failure to file was the direct result of a mental illness or disability that rendered [him] incapable of rational thought, incapable of deliberate decision making, incapable of handling [his] own affairs, or unable to function in society." Id. at 1381. A lack of knowledge of an actionable claim is not a basis for equitable tolling. Id. at 1380 (citing Cloer, 654 F.3d at 1344-45).

While the records show that petitioner had anxiety and depression and a mental health condition beginning approximately 2005 and 2006, there is no evidence that these conditions rendered him mentally incapacitated prior to his hospital admission in October 2013. For example, petitioner's college transcript shows he was able to regularly attend classes, complete his classes, and complete college in May 2010. On February 23, 2012, petitioner was evaluated by a health care provider and assessed with having appropriate thought processes and intact judgment and insight. Pet. Ex. 6 at 24.

The onset of petitioner's irrational thoughts occurred on or about October 1, 2013,[40] shortly before his psychiatric admission on October 4, 2013. On admission to Zucker Hillside Hospital, petitioner had delusions and was assessed with poor insight and judgment. Pet. Ex. 12 at 3. He was diagnosed with schizoaffective disorder and bipolar disorder as reflected in his discharge paperwork dated October 21, 2013. Id. at 12. There were periods of time in 2013 and 2014 where his symptoms resolved. However, in January 2014, when seen in an emergency room, he was noted to have poor insight and judgment. Id. at 23-25.

Moving forward in time, on December 21, 2016, Nurse Practitioner, Ms. Widen, noted petitioner was in "no apparent distress," alert, and oriented to time, person, and place. Pet. Ex. 15 at 3. On August 1, 2018, petitioner appeared and testified at his disability hearing. The administrative judge did not document that petitioner was incapable of rational thought or

[40] October 1, 2013 is the date that petitioner was determined to be disabled and entitled to social security disability. See Pet. Ex. 19 at 2, 6.

deliberate decision-making, or incapable of handling his own affairs, or unable to function in society. Likewise, Dr. Guram, on December 13, 2018, saw petitioner and did not document anything that implied that petitioner was incapable of rational thought or deliberate decision-making, or incapable of handling his own affairs, or unable to function in society.

Therefore, the evidence supports petitioner's allegation that the onset of his mental incapacity began on October 1, 2013.[41] The undersigned is not making a finding as to petitioner's alleged incapacity period[42] because it is not relevant to the undersigned's decision for the reasons described below.

2. Application of Equitable Tolling in This Case

As described above, petitioner's statute of limitations expired in 2009. Petitioner's evidence shows that his period of mental incapacity did not begin until October 1, 2013. Prior to October 1, 2013, there is no evidence of extraordinary circumstances that prevented petitioner from filing his petition.

Petitioner cannot use the doctrine of equitable tolling based on mental incapacity where his period of incapacity did not begin until four years after the statute of limitations expired. Because the statute of limitations expired before petitioner's incapacity began on October 1, 2013, the question of whether equitable tolling applies is irrelevant.

Moreover, petitioner did not provide evidence to show that he diligently pursued his rights as required in order to make a finding of equitable tolling. K.G., 951 F.3d at 1381 (finding "the proper analysis of equitable tolling based on mental incapacity in the Vaccine Act context must consider both extraordinary circumstances and diligence"). An allegation that petitioner and/or his parents did not know of the Vaccine Program is insufficient.[43] Id. at 1380. Thus, petitioner failed to establish that (1) he pursued his rights diligently and (2) an extraordinary circumstance prevented him from timely filing his claim within 36 months of onset of any conditions alleged in his petition.

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[41] See Pet. Response at 2. The evidence preponderates in favor of petitioner's contention that he was "incapable of rational thought, incapable of deliberate decision making, incapable of handling [his] own affairs, or unable to function in society" on October 1, 2013. K.G., 951 F.3d at 1381.

[42] Petitioner alleges he "has been mentally incapacitated from October 1, 2013 until present day." Pet. Response at 2.

[43] Petitioner states that his parents did not know about the Vaccine Program. Pet. Mot. to Proceed at 14. However, the undersigned makes no finding with regard to whether or not petitioner or his parents diligently pursued his rights because she finds the question of equitable tolling is not relevant here. Thus, the question of whether petitioner diligently pursued his rights is not relevant.

VI. CONCLUSION

It is clear from the medical records that petitioner has had a very difficult struggle with mental illness, and the undersigned has great sympathy for what he has endured due to his illness. The undersigned's decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

For all of the reasons discussed above, the undersigned **GRANTS** respondent's motion to dismiss and **DISMISSES** petitioner's case for failure to file a timely action pursuant to Section 16(a) of the Vaccine Act. In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master